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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,478	07/31/2001	Andrea Pizzariello		1759

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STETINA BRUNDA GARRED & BRUCKER
75 ENTERPRISE, SUITE 250
ALISO VIEJO, CA 92656

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,478	PIZZARIELLO ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31 July 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0731/2001.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: IDS of 01042002.

DETAILED ACTION

Claim Objections

1. Claim 14 is objected to because of the following informality: in line 10 -- to – should be inserted after "proportional."

2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1, line 14: -- and -- should be inserted after "electrode;";

b) Claim 1, last line: "being" should be placed after "electrodes";

c) Claims 1-5 and 8: the last element in a Markush group should be preceded with --- and --;

4. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-7, 9-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulys et al. ("Glucose biosensor based on the incorporation of Meldola Blue and glucose oxidase within carbon paste," *Analytica Chimica Acta* 288 (1994) 193-196), hereafter "Kulys."

Addressing claim 1, Kulys teaches an amperometric biosensor system for the detection of analytes (abstract) comprising

a) at least one biocatalyst (glucose oxidase (first full paragraph in the first column on page 194)) producing a pH change by its interaction with the analyte (first full paragraph in the second column on page 195);

b) at least one compound exhibiting different redox properties in its protonated and non-protonated forms (first full paragraph in the second column on page 194) consisting of a heterocyclic compound containing between 3 to 30 carbon atoms and N and O heteroatoms and substituted with $-NR_1R_2$, wherein R_1 and R_2 are hydrocarbon chains (see the structure for Meldola Blue in the ACS Registry print-out);

c) a working electrode (second full paragraph in the second column on page 194); and

d) a reference electrode (last paragraph in the second column on page 194);

said electrodes being connected through an ammeter (implied by the last paragraph in the second column on page 194 and Figure 1, which disclose measuring current).

Addressing claims 2, 3, and 5, Kulys discloses the enzyme glucose oxidase (glucose oxidase (first full paragraph in the first column on page 194)).

Addressing claim 6, in Kulys the pH-sensitive redox compound is Meldola Blue, which is a "monomer" (a non-polymerized compound).

Addressing claim 7, Meldola Blue is a phenoxazine (Kulys abstract).

Addressing claim 9, the working electrode is a solid composite electrode (first and second full paragraphs in the second column on page 194 of Kulys).

Addressing claim 10, the reference electrode is a calomel electrode (last full paragraph in the second column on page 194 of Kulys).

Addressing claim 11, Kulys discloses at least detecting glucose (abstract).

Addressing claim 12, Kulys discloses at least steps (a)-(e) (last full paragraph in the second column on page 194; first paragraph of Results and Discussion on page 195; and Figure 2 of Kulys). Note that step (e) is optional.

Addressing claim 13, Kulys discloses at least steps (a)-(e) (last full paragraph in the second column on page 194; first paragraph of Results and Discussion on page 195; and Figures 1 and 2 of Kulys). Note that step (e) is optional.

Addressing claim 16, Kulys discloses measuring glucose, which has use in at least human and veterinary diagnostics.

7. Claims 1-3, 5, 6, 10, 11, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishizawa et al. ("Penicillin Sensor Based on a Microarray Electrode Coated with pH-Responsive Polypyrrole," *Anal. Chem.* 1992, 664, 2642-2644), hereafter "Nishizawa."

Addressing claim 1, Nishizawa teaches an amperometric biosensor system for the detection of analytes (Introduction) comprising

a) at least one biocatalyst (penicillase (Figure 1)) producing a pH change by its interaction with the analyte (first full paragraph in the second column on page 2643);

b) at least one compound exhibiting different redox properties in its protonated and non-protonated forms (Figure 1 and the second full paragraph in the first column on page 2643) consisting of a heterocyclic compound containing between

3 to 30 carbon atoms and N heteroatom (see the structure for polypyrrole in the abstract of US 5,795,953));

c) a working electrode (Figure 1); and

d) a reference electrode (Figure 1);

said electrodes being connected through an ammeter (implied by Figure 2, which discloses measuring current).

Addressing claims 2, 3, and 5, Nishizawa discloses the enzyme penicillase (Figure 1)).

Addressing claim 6, in Nishizawa the pH-sensitive redox compound is polypyrrole, which is a polymer.

Addressing claim 10, in Nishizawa the reference electrode is a calomel electrode (last full paragraphs in the second column on page 2642).

Addressing claim 11, Nishizawa discloses at least detecting penicillin (abstract).

Addressing claim 16, Nishizawa discloses measuring penicillin, which has use in at least the pharmaceutical industry.

8. Claims 1-3, 6-12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Castaño et al. ("Amperometric detection of ethanol with poly-(o-phenylenediamine)-modified enzyme electrodes," *Biosensors & Bioelectronics* vol. 12, no. 6, pp. 511-520), hereafter "Castaño."

Addressing claim 1, Castaño teaches an amperometric biosensor system for the detection of analytes (abstract and Figure 1) comprising

a) at least one biocatalyst (enzyme ADH (abstract and first paragraph in the first column on page 514)) producing a pH change by its interaction with the analyte (equation (1) in the first column on page 514);

b) at least one compound exhibiting different redox properties in its protonated and non-protonated forms (NAD (first equation in the first column on page 514)) consisting of a heterocyclic compound containing between 3 to 30 carbon atoms and N heteroatom (see the structure for NAD in the ACS Registry print-out) *and* poly(o- phenylenediamine) (for the structure of poly(o- phenylenediamine) see the last sentence in the second column on page 391 and the top of page 392 of Karalemas et al. ("Construction of a L-lysine biosensor by immobilizing lysine oxidase on a gold-poly(o-phenylenediamine) electrode)," *Talanta* 53 (2000), 391-402). For the effect of pH on a poly(o-phenylenediamine) electrode see Figure 3 of Lobo et al. ("Electrocatalytic detection of nicotinamide coenzymes by poly(o-aminophenol)- and poly(o-phenylenediamine)-modified carbon paste electrodes), *Analytica Chimica Acta* 325 (1996) 33-42);

c) a working electrode (Apparatus in first column on page 513); and

d) a reference electrode (Apparatus in first column on page 513);

said electrodes being connected through an ammeter (implied by Apparatus in first column on page 513 and Figure 1, which disclose measuring current).

Addressing claims 2 and 3, Casta ón discloses the enzyme alcohol dehydrogenase (Electrode preparation on page 512), which is an oxidoreductase.

Addressing claims 6-8, Casta ón discloses the pH-sensitive "monomer" nicotimanide adenine dinucleotide and the pH-sensitive polymer poly(o-phenylenediamine).

Addressing claim 9, the working electrode is a solid composite electrode (Electrode preparation on page 513 of Casta ón bridging to page 513).

Addressing claim 10, the reference electrode is a Ag/AgCl electrode (Electrode preparation on page 513 of Casta ón bridging to page 513).

Addressing claim 11, Casta ón discloses at least detecting ethanol (abstract).

Addressing claim 12, Casta ón discloses at least steps (a)-(e) (Analytical procedure on page 513 and Figure 7). Note that step (e) is optional.

Addressing claim 16, Castagnon discloses measuring ethanol, which has use in at least the agro-food industry.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishizawa et al. ("Penicillin Sensor Based on a Microarray Electrode Coated with pH-Responsive Polypyrrole," *Anal. Chem.* 1992, 664, 2642-2644), hereafter "Nishizawa."

Nishizawa teaches an amperometric biosensor system for the detection of analytes (Introduction) comprising

a) at least one biocatalyst (penicillase (Figure 1)) producing a pH change by its interaction with the analyte (first full paragraph in the second column on page 2643);

b) at least one compound exhibiting different redox properties in its protonated and non-protonated forms (Figure 1 and the second full paragraph in the first column on page 2643) consisting of a heterocyclic compound containing between 3 to 30 carbon atoms and N heteroatom (see the structure for polypyrrole in the abstract of US 5,795,953));

c) a working electrode (Figure 1); and

d) a reference electrode (Figure 1);

said electrodes being connected through an ammeter (implied by Figure 2, which discloses measuring current).

Although Nishizawa teaches penicillinase, Nishizawa does not specifically mention any of the enzymes listed in the Markush group of claim 4. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to use other enzymes such as those listed in Applicant's claim 4, depending on the analyte or interest, because Nishizawa states, "[s]ince many enzymes bring about pH changes through their catalytic reactions, the principle proposed here will widely by applicable to the fabrication of enzyme-based microelectrochemical devices which detect biologically important substances" (second column on page 2644).

Allowable Subject Matter

12. Claims 14 and 15 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 14: the nonobvious limitations in the combination of limitations are the requirements of steps (e) and (f), which require adding inhibiting-analyte to the measuring solution and measuring a current change that is proportional to the inhibiting-analyte concentration. In Kulys, Nishizawa, and Casta on the biocatalyst substrate is the analyte (e.g., in Kulys the biocatalyst is glucose

oxidase and the analyte is glucose). There is also no suggestion that if the analyte were an agent that would inhibit the biocatalyst then the current change would be proportional to the inhibiting-analyte concentration;

a) Claim 15: the nonobvious limitations in the combination of limitations are the requirements of steps (d) and (e), which require adding inhibiting-analyte to the measuring solution and measuring a current change that is proportional to the inhibiting-analyte concentration. In Kulys, Nishizawa, and Casta on the biocatalyst substrate is the analyte (e.g., in Kulys the biocatalyst is glucose oxidase and the analyte is glucose). There is also no suggestion that if the analyte were an agent that would inhibit the biocatalyst then the current change would be proportional to the inhibiting-analyte concentration;

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
July 6, 2004